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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,481	01/20/2004	Nozer M. Mehta	P/546-280	2921

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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,481	MEHTA ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61,63 and 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-60,63 and 65* is/are rejected.

7)☒ Claim(s) *61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claim 61 is objected to because of the following informalities: At claim 61, line 2, "hormone comprising" should be written as two separate words. Appropriate correction is required.

2. The effective filing date of instant claims 1-61 and 63 is January 21, 2003, the filing date of provisional application 60/441,856. Instant claims 1-61 and 63 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the provisional application because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

The effective filing date of instant claim 65 is January 20, 2004, the filing date of the instant application. Instant claim 65 is not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/441,856 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose general pharmaceutical compositions for oral delivery in which the PTH 1-34-OH are not amidated.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-8, 12-47, 49-51, 54-60, 63, and 65 are rejected under 35 U.S.C. 103(a) as being obvious over Stern et al (U.S. Patent No. 6,086,918) in view of Habener (U.S. Patent No. 5,120,712), Balschmidt et al (U.S. Patent No. 5,157,021), Barbier et al (U.S. Patent No. 6,110,892), the European Patent Application 878,201, or Neiss et al (U.S. Patent No. 4,804,742). Stern et al teach oral administration of peptides such as insulin, salmon calcitonin, parathyroid hormone, and lhrf using a carrier comprising a pH-lowering agent, an absorption enhancer, a non-physiologically active protein, a gelatin capsule, and an enteric coating. See, e.g., column 6,

line 1 - column 12, line 10, and claims 1-55. Stern et al do not teach peptides which are amidated GLP-1 analogs, amidated insulin analogs, or amidated PTH analogs. Habener teaches GLP-1 analogs which are amidated. See, e.g., claims 1 and 4. Balschmidt et al teach insulin in which the carboxylic acid groups present in the sidechains at residues A4, A17, B13, and B21 are amidated in order to achieve a long-lasting protracted acting insulin analog. See, e.g., column 2, lines 5-8 and 49-53. Barbier et al teach the human parathyroid hormone derivatives hPTH(1-34)-OH and hPTH(1-31)NH_2. See, e.g., column 2, lines 26-44. The European Patent Application '201 teaches the human parathyroid hormone derivative hPTH(1-34)NH_2. See, e.g., column 3, lines 31-36. Neiss et al teach salmon calcitonin amidated at locations which are not naturally amidated and which have extended duration of activity. See, e.g., column 1, lines 42-44, and claims 1 and 2. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al in the oral administration compositions of Stern et al because the oral administration compositions of Stern et al have general applicability to any peptide and because it would be desirable to be able to administer orally the peptides of Habener, Balschmidt et al, Barbier, the European Patent Application '201, and Neiss et al because oral administration is easier for the patient. Applicants' claims would have been prima facie obvious at the time the invention was made because applying Stern et al's known and generally applicable technique, i.e. of combining peptides with a pH-lowering agent, an absorption enhancer, a non-physiologically active protein, a gelatin capsule, and an enteric coating so that the peptides can be administered orally, to the known and specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al,

with only the expected result that the known and specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al can be administered orally, is prima facie obvious. See KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (S. Ct. 2007). With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

5. Claims 5 and 48 are rejected under 35 U.S.C. 103(a) as being obvious over Stern et al (U.S. Patent No. 6,086,918) in view of Habener (U.S. Patent No. 5,120,712), Barbier et al (U.S. Patent No. 6,110,892), the European Patent Application 878,201, or Neiss et al (U.S. Patent No. 4,804,742) as applied against claims 1-8, 12-47, 49-51, 54-60, 63, and 65 above, and further in view of Stern et al (U.S. Patent No. 5,912,014). Habener, Barbier et al, the European Patent Application '201, and Neiss et al teach known and specific peptides which are amidated at their C-termini, but do not teach synthesizing these peptides by forming glycine-extended precursors and then converting the glycine residue to a C-terminal amide group. Stern et al '014 teaches salmon calcitonin made with a C-terminal glycine extension which is enzymatically converted to an amide group. See, e.g., column 5, lines 12-23. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the known and specific peptides of Habener, Barbier et al, the European Patent Application '201, or Neiss et al for use in the oral administration compositions of Stern et al '918 by synthesizing the peptides as glycine-extended precursors and then converting the glycine residue to a C-terminal amide group, because Stern et al '014 teach that this is a known reaction technique for forming a C-terminally amidated peptide, and because the particular method of synthesizing a peptide would

not have been expected to affect the in vivo activity of the peptide.

6. Claims 1-47, 49-60, 63, and 65 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 02/043767 in view of Habener (U.S. Patent No. 5,120,712), Balschmidt et al (U.S. Patent No. 5,157,021), Barbier et al (U.S. Patent No. 6,110,892), the European Patent Application 878,201, or Neiss et al (U.S. Patent No. 4,804,742). The WO Patent Application '767 teaches oral administration of peptides such as insulin, salmon calcitonin, parathyroid hormone, lhrf, and GLP-1 linked to a membrane translocator using a carrier comprising a pH-lowering agent, a protease inhibitor, an absorption enhancer, a non-physiologically active peptide, a gelatin capsule, and an enteric coating. See, e.g., page 17, lines 13-22, page 18, lines 10-27, page 20, lines 11-29, and claims 1-57. [Note that the WO Patent Application '767 does not designate the US, and therefore is not available as prior art under 35 U.S.C. 102(e).] The WO Patent Application '767 does not teach peptides which are amidated GLP-1 analogs, amidated insulin analogs, or amidated PTH analogs. Habener teaches GLP-1 analogs which are amidated. See, e.g., claims 1 and 4. Balschmidt et al teach insulin in which the carboxylic acid groups present in the sidechains at residues A4, A17, B13, and B21 are amidated in order to achieve a long-lasting protracted acting insulin analog. See, e.g., column 2, lines 5-8 and 49-53. Barbier et al teach the human parathyroid hormone derivatives hPTH(1-34)-OH and hPTH(1-31)NH_2. See, e.g., column 2, lines 26-44. The European Patent Application '201 teaches the human parathyroid hormone derivative hPTH(1-34)NH_2. See, e.g., column 3, lines 31-36. Neiss et al teach salmon calcitonin amidated at locations which are not naturally amidated and which have extended duration of activity. See, e.g., column 1, lines 42-44, and claims 1 and 2. It would have been obvious to one of ordinary skill in the art at the time

Applicant's invention was made to use the specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al in the oral administration compositions of the WO Patent Application '767 because the oral administration compositions have general applicability to any peptide and because it would be desirable to be able to administer orally the peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, and Neiss et al because oral administration is easier for the patient. Applicants' claims would have been prima facie obvious at the time the invention was made because applying the WO Patent Application '767's known and generally applicable technique, i.e. of combining peptides with a pH-lowering agent, a protease inhibitor, an absorption enhancer, a non-physiologically active peptide, a gelatin capsule, and an enteric coating so that the peptides can be administered orally, to the known and specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al, with only the expected result that the known and specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al can be administered orally, is prima facie obvious. See KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (S. Ct. 2007). With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

7. Claims 5 and 48 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 02/043767 in view of Habener (U.S. Patent No. 5,120,712), Barbier et al (U.S. Patent No. 6,110,892), the European Patent Application 878,201, or Neiss et al (U.S. Patent No. 4,804,742) as applied against claims 1-47, 49-60, 63, and 65 above, and further in

view of Stern et al (U.S. Patent No. 5,912,014). Habener, Barbier et al, the European Patent Application '201, and Neiss et al teach known and specific peptides which are amidated at their C-termini, but do not teach synthesizing these peptides by forming glycine-extended precursors and then converting the glycine residue to a C-terminal amide group. Stern et al '014 teaches salmon calcitonin made with a C-terminal glycine extension which is enzymatically converted to an amide group. See, e.g., column 5, lines 12-23. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the known and specific peptides of Habener, Barbier et al, the European Patent Application '201, and Neiss et al for use in the oral administration compositions of the WO Patent Application '767 by synthesizing the peptides as glycine-extended precursors and then converting the glycine residue to a C-terminal amide group, because Stern et al '014 teaches that this is a known reaction technique for forming a C-terminally amidated peptide, and because the particular method of synthesizing a peptide would not have been expected to affect the in vivo activity of the peptide.

8. Claims 1, 6, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Balschmidt et al (U.S. Patent No. 5,157,021). Balschmidt et al teach pharmaceutical compositions comprising insulin in which the carboxylic acid groups present in the sidechains at residues A4, A17, B13, and B21 are amidated in order to achieve a long-lasting protracted acting insulin analog. See, e.g., column 2, lines 5-8 and 49-53; column 3, line 64 - column 4, line 3; and claims 1-16. Note that an intended use limitation, e.g., "orally delivered", does not impart patentability to product claims where the product is otherwise anticipated by the prior art. Because Balschmidt et al teach the only component specified in Applicants' claims, i.e. an active peptide amidated at a location that is not naturally amidated, inherently the composition of

Balschmidt et al will provide enhanced bioavailability of the amidated peptide when it is orally delivered to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the pharmaceutical compositions of Balschmidt et al and Applicants' claimed compositions to shift the burden to Applicants to provide evidence that the claimed compositions are unobviously different than those of Balschmidt et al.

9. Claims 1, 4, 5, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Habener (U.S. Patent No. 5,120,712). Habener teaches pharmaceutical compositions comprising GLP-1 analogs which are amidated at the C-terminus. See, e.g., column 4, lines 14-29, and claims 1, 4, 5, and 7. Note that an intended use limitation, e.g., "orally delivered", does not impart patentability to product claims where the product is otherwise anticipated by the prior art. Because Habener teaches the only component specified in Applicants' claims, i.e. an active peptide amidated at a location that is not naturally amidated, inherently the composition of Habener will provide enhanced bioavailability of the amidated peptide when it is orally delivered to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the pharmaceutical compositions of Habener and Applicants' claimed compositions to shift the burden to Applicants to provide evidence that the claimed compositions are unobviously different than those of Habener. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

10. Claims 1, 4, 5, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Barbier et al (U.S. Patent No. 6,110,892). Barbier et al teach pharmaceutical compositions comprising hPTH(1-31)NH_2. See, e.g., column 9, lines 25-46. Note that an intended use

limitation, e.g., "orally delivered", does not impart patentability to product claims where the product is otherwise anticipated by the prior art. Because Barbier et al teach the only component specified in Applicants' claims, i.e. an active peptide amidated at a location that is not naturally amidated, inherently the composition of Barbier et al will provide enhanced bioavailability of the amidated peptide when it is orally delivered to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the pharmaceutical compositions of Barbier et al and Applicants' claimed compositions to shift the burden to Applicants to provide evidence that the claimed compositions are unobviously different than those of Barbier et al. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

11. Claims 1, 4, 5, 40, 42, 45, 47, 58, 60, and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Peri et al (U.S. Patent Application Publication 2004/0023882). Peri et al teach pharmaceutical compositions comprising hPTH(1-34) amidated at its C-terminus, including hPTH(1-34)NH_2. The compositions can be administered orally. See, e.g., paragraph [0064] and claims 1-2. Because Peri et al teach the only component specified in Applicants' claims, i.e. an active peptide amidated at a location that is not naturally amidated, inherently the composition of Peri et al will provide enhanced bioavailability of the amidated peptide when it is orally delivered, e.g., as a result of enhanced intestinal absorption, to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the pharmaceutical compositions of Peri et al and Applicants' claimed compositions to shift the burden to Applicants to provide evidence that the claimed compositions are unobviously

different than those of Peri et al. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

The subject matter disclosed by Peri et al and relied upon in the rejection is also disclosed in the provisional application, 60/378,082, upon which Peri et al claim priority under 35 U.S.C. 119(e). See, e.g., page 10, line 22, and claims 1 and 2 of the provisional application. Accordingly, Peri et al is available as prior art against the instant claims under 35 U.S.C. 102(e).

12. Applicant's arguments filed June 6, 2008 have been fully considered but they are not persuasive.

The declaration under 37 CFR 1.132 by Inventor Stern filed June 6, 2008 has been carefully considered but is not deemed to overcome the rejections under 35 U.S.C. 103(a) set forth in this Office action. The declaration asserts that Examples 1-4 of the specification demonstrate that bioavailability of orally administered peptides is unexpectedly enhanced when the peptides are amidated at a location that is not naturally amidated. However, in Example 1 of the specification, the two tested peptides, i.e. sCTgly and sCT-NH_2, do not differ from one another merely by the absence or presence of an amide group. Rather, the tested peptide representative of Applicants' claimed invention, sCT-NH_2, differs not only by amidation but also by removal of the C-terminal amino acid of sCTgly. Because of these two differences between the tested peptides, it is not possible to conclude that the demonstrated differences in bioavailability are the result of the claimed limitation "amidated at a location that is not naturally amidated". Similarly with respect to Example 2 of the specification, the tested peptide representative of Applicants' claimed invention, PTH(1-31)NH_2, differs from the comparative

peptide not only because of the presence of the amide group but also because of the absence of three amino acids from the C-terminus of the peptide. In comparative testing, when multiple variables are changed throughout the tests (e.g., amino acid sequence and amidation state), it is not possible to conclude that a single variable (e.g., amidation state) is responsible for the difference in results. With respect to Example 3 of the specification, while the two peptides tested differ only with respect to their amidation state, the peptides are intraduodenally administered rather than orally administered as is required by the claims. Declarant has not established that intraduodenal administration will accurately predict bioavailabilities of orally administered peptides. With respect to Example 4 of the specification, the test involves LHRH which is amidated at a location that is naturally amidated, i.e. tests a peptide which is not embraced by any of the claims. Accordingly, there is no nexus between the results reported in Example 4 and the instant claims.

With respect to Example 3, if Applicants and/or Declarant were to establish that the differences in bioavailability shown for intraduodenal administration were predictive of differences in bioavailability for oral administration, the examiner agrees that the example would demonstrate unexpected results for the tested peptide, PTH1-34NH_2. However, a single comparative results will not be deemed to be commensurate in scope with claims not limited to PTH1-34NH_2. In view of the vast number of physiologically active peptide agents, many of which comprise plural non-natural amidation sites, testing of a single species will not be considered to be predictive of unexpected results for the entire genus of claimed peptides.

To the extent that the Stern declaration is intended to demonstrate a showing of long-felt need and failure of others, see MPEP 716.04. The Stern declaration clearly does not satisfy the evidentiary requirements set forth in the cited section of the MPEP.

The anticipation rejection based upon Balschmidt et al (U.S. Patent No. 5,157,021) is maintained. Applicants contend that "oral pharmaceutical composition… requires that the composition have certain features/attributes which are clearly set forth in the written description of the invention and which, therefore, need not be specifically recited in the claim". The examiner does not agree with Applicants' interpretation of the claim limitation "oral pharmaceutical composition" or with the procedure with which Applicants intend to interpret the claim limitation. During prosecution, claims are interpreted as broadly as their terms reasonably allow. See MPEP 2111.01(I). Applicants have not clearly set forth a definition of the phrase in the specification. See MPEP 2111.01(IV). Limitations which are found only in the specification will not be read into the claims. See MPEP 2111.01(II).

It is noted that Applicants have not identified which particular features of the disclosure are required by the claim terminology "oral pharmaceutical composition". There is some suggestion at page 17, lines 2-4, of the response that "oral pharmaceutical composition" requires the presence of at least one of a pH-lowering agent and a protease inhibitor, an acid -resistant protective vehicle, plus some unnamed features encompassed under "etc.". However, assuming arguendo that Applicants' argument is accepted, then the recitation of these same particular features, e.g., in dependent claims 2 and 3, is redundant. Claim language should not be interpreted so as to render dependent claims redundant and duplicative. Further, if certain specific features of the specification are to be read into the claims, it is not clear why other

specific features of the specification should not also be read into the claims. For example, it could analogously be argued that the claims should be limited to the particular peptide tested in Example 3. Applicants have provided no procedures or guidelines with which it can be determined whether particular features disclosed in the specification constitute claim limitations or not. The analysis which Applicants' argument would entail is avoided by a requirement that those limitations which Applicants intend to define the metes and bounds of their claims be recited in the claims.

As to the interpretation of "oral pharmaceutical composition", the examiner's position is that the only functional and/or structural limitation this imparts to the claims is that the composition must be capable of being administered orally, i.e. of being swallowed. The injectable formulations of Balschmidt et al, i.e. solutions, are capable of being swallowed and are therefore "oral pharmaceutical compositions" as claimed by Applicants. Again, it is irrelevant that Balschmidt et al do not actually intend to administer their formulations orally, because the claims at issue are product claims, and are not drawn to methods of oral administration.

The anticipation rejections based upon Habener (U.S. Patent No. 5,120,712) and upon Barbier et al (U.S. Patent No. 6,110,892) are maintained for reasons analogous to those set forth above with respect to Balschmidt et al (U.S. Patent No. 5,157,021).

The anticipation rejection based upon Peri et al (U.S. Patent Application Publication 2004/0023882) is maintained. Applicants contend that the hPTH(1-34)NH_2 of Peri et al is not amidated at a location that is not naturally amidated. However, at page 16, lines 1-10, and Example 3 of the specification, and at claim 42, Applicants exemplify hPTH(1-34)NH_2 as constituting an amidated peptide according to the invention. Further, sections 10 and 11 of the

declaration under 37 CFR 1.132 by Inventor Stern filed June 6, 2008 identify amidated PTH 1-34 as constituting an amidated peptide according to the invention. To the extent that Attorney's arguments contradict the claims, specification, and statements of the inventor, the arguments can not be accepted. With respect to the method claims, the examiner contends in the rejection that Peri et al inherently teach enhanced bioavailability. Applicants have not rebutted this argument of inherency by submission of evidence or by a showing that the similarity between Peri et al and Applicants' claims as alleged by the examiner does not in fact exist. Note that a mere difference in descriptive terminology is not sufficient to impart patentability (see In re Skoner, 186 USPQ 80, 82 (CCPA 1975)), and that a result need not be recognized or suggested by the prior art in order to be inherent (see MPEP 2112(II)).

13. Claim 61 would be allowable if rewritten or amended to overcome the claim objection set forth in this Office action.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
July 29, 2008